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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/891,983	06/26/2001	Dinesh O. Shah	6821.US.01	9651

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EXAMINER

LUCAS, ZACHARIAH

ART UNIT PAPER NUMBER

1648

DATE MAILED: 07/06/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No. 09/891,983	Applicant(s) SHAH ET AL.	
Examiner Zachariah Lucas	Art Unit 1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 12 May 2005.
- 2a) This action is FINAL.
- 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 8 and 9 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 8 and 9 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: _____

DETAILED ACTION

Status of the Claims

1. Currently, claims 8 and 9 are pending in the application. In the Final action, mailed on July 13, 2004, claims 1-6, 8, 9, 13, 14, 18-21, and 23-25 were pending with claims 1-6, 8, 9, 13, 14, and 23-25 rejected; and claims 18-21 withdrawn as to non-elected inventions. In an After Final amendment (entered) filed on October 13, 2004, the Applicant amended claims 1, 5, and 8; and cancelled claims 3, 13, 14, and 23-25. In an Advisory action, mailed on November 3, 2004, the rejection of claims 1, 2, and 4-6 was maintained, and claims 8 and 9 were indicated as allowable. A subsequence amendment was filed on March 3, 2003, in which claims 1, 2, 4-6 were cancelled, leaving only claims 8 and 9 pending in the application.
2. Upon subsequent review of the application, certain problems regarding the availability of the antibodies used in the methods of claims 8 and 9 were noted. The rejection in this action addresses the issue.
3. Because this action raises a new ground of rejection, the Finality of the prior action is withdrawn, and the present action is made Non-Final.

Claim Objections

4. **(Prior Objection- Withdrawn)** Claim 25 was objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. In view of the cancellation of the claim from the application, the objection is withdrawn.

Claim Rejections - 35 USC § 112

5. **(Prior Rejection- Withdrawn)** Claims 8 and 9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 8 is treated as representative. The rejection was withdrawn in the Advisory action of November 4, 2004 in Response to the amendment of October 13, 2004.

6. **(Prior Rejection- Withdrawn)** Claim 25 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In view of the cancellation of the claim, the rejection is withdrawn.

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. **(Prior Rejection- Withdrawn)** Claims 8 and 9 were rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claims were rejected for lacking enablement for the use of the C11-10 antibody for detecting other anti-HCV antibodies. The rejection was withdrawn in the Advisory action of November 4, 2004 in Response to the amendment of October 13, 2004.

9. **(Prior Rejection- Withdrawn)** Claims 8 and 9 were rejected under 35 U.S.C. 112, first paragraph, as failing provide written description support for the use of the C11-10 antibody to detect anti-HCV antibody bound to the antigen coated on a solid phase in subpart (a)(1) of the

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claimed method. The rejection was withdrawn in the Advisory action of November 4, 2004 in Response to the amendment of October 13, 2004.

10. **(New Rejection)** Claims 8 and 9 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The antibodies C11-14 and C11-10 are required to practice the claimed invention because they are needed to perform the claimed method. As a required element, it must be known and readily available to the public or obtainable by a repeatable method set forth in the specification, or otherwise readily available to the public. If it is not so obtainable or available, the enablement requirements of 35 U.S.C. § 112, first paragraph, may be satisfied by a deposit of the materials. See 37 CFR 1.802. One cannot practice the claimed invention without the antibodies. Therefore, access to them is required to practice the invention. The specification does not provide a repeatable method for readily identifying the antibodies without access to the hybridomas indicated as deposited with the National Institute of Bioscience and Human Technology as FERM BP-6004 (C11-10) and FERM BP-6006 (C11-14) and it does not appear to be readily available material.

Deposit of the antibodies or a hybridoma in a recognized deposit facility would satisfy the enablement requirements of 35 U.S.C. 112, because the strains would be readily available to the public to practice the invention claimed, see 37 CFR 1.801- 37 CFR 1.809.

If a deposit is made under the terms of the Budapest Treaty, then an affidavit or declaration by applicants or someone associated with the patent owner, who is in a position to make such assurances, or a statement by an attorney of record over his or her signature, stating that the deposit has been made under the terms of the Budapest Treaty and that all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent, would satisfy the deposit requirements. See 37 CFR 1.808.

If a deposit is not made under the terms of the Budapest Treaty, then an affidavit or declaration by applicants or someone associated with the patent owner who is in a position to make such assurances, or a statement by an attorney of record over his or her signature, stating that the deposit has been made at an acceptable depository and that the following criteria have been met:

- (a) during the pendency of this application, access to the invention will be afforded to one determined by the Commissioner to be entitled thereto;
- (b) all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon granting of the patent;

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(c) the deposit will be maintained for a term of at least thirty (30) years and at least five (5) years after the most recent request for the furnishing of a sample of the deposited material;

(d) a viability statement in accordance with the provisions of 37 CFR 1.807;
and

(e) the deposit will be replaced should it become necessary due to inviability, contamination or loss of capability to function in the manner described in the specification.

It is noted that mere reference to a deposit or the biological material in any document is not sufficient to demonstrate public availability. Thus, the fact that the antibodies appear to be referenced as deposited in U.S. Patent 6,623,921 (columns 20-22), and in WO 99/06836 (pages 7-8) does not demonstrate public availability, and therefore does not meet avoid the necessity for the deposit requirement.

It is further noted that there is no identification of any of the information required under 37 CFR 1.809(d) in the present application. The specification should be amended to contain:

- (1) The accession number for the deposit;
- (2) The date of the deposit;
- (3) A description of the deposited biological material sufficient to specifically identify it and to permit examination; and
- (4) The name and address of the depository.

See 37 CFR 1.803 - 37 CFR 1.809 for additional explanation of these requirements.

Claim Rejections - 35 USC § 102

11. **(Prior Rejection- Withdrawn)** Claims 1, 2, 5, and 6 were rejected under 35 U.S.C. 102(b) as being anticipated by Aoyagi et al. (WO 00/07023, the English language translation of is found as U.S. Patent 6,623,921). In view of the cancellation of these claims from the application, the rejection is withdrawn.

Claim Rejections - 35 USC § 103

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12. **(Prior Rejection- Withdrawn)** Claims 13 and 14 were rejected under 35 U.S.C. 103(a) as being unpatentable over Aoyagi (WO 00/07023- as translated in U.S. Patent 6,623,921) in view of Mehta et al. (US Patent 5,753,430). In view of the cancellation of these claims from the application, the rejection is withdrawn.

13. **(Prior Rejection- Withdrawn)** Claims 23-25 were rejected under 35 U.S.C. 103(a) as being unpatentable over Aoyagi as applied to claims 13 and 14 in the prior action. These claims have been described above. In view of the cancellation of these claims from the application, the rejection is withdrawn.

Conclusion

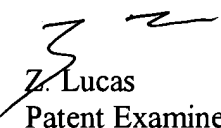
14. No claims are allowed. As indicated in the prior action, and argued by the Applicant in the Response filed on May 24, 2004 (received by Office May 28, 2004), the method of claims 8 and 9 show unexpected results over the prior art. The claimed method therefore appears patentable over the prior art.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachariah Lucas whose telephone number is 571-272-0905. The examiner can normally be reached on Monday-Friday, 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Z. Lucas
Patent Examiner



JEFFREY STUCKER
PRIMARY EXAMINER